K041919 1 of 2

510(k) Notification

Section E. Summary as required by section 807.92 (c)

Submitter: Clinico GmbH
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Date: 07 / 07 / 2004

Name of Device: Perfudrop® Air M-P With Needle

Common name: Intravascular administration set

Classification name of device:
a) Product code: FPA
b) Regulation number: 880.5440

Predicate device: Gemini IV Administration Sets, Alaris (Premarket notification K022209)

Description of the set: The Perfudrop® Air M-P intravascular administration set (model no. 48451606) is a disposable, single-use Intravascular administration set intended for use under gravity and pressure conditions as well. The intravascular administration set uses a needle attached to the set.

The design of the intravascular administration set is according to the requirements of ISO 8536-4.
The design of the sterile hypodermic needle is according to the requirements of ISO 7864.

Intended use of the device:	Perfudrop® Air M-P with needle is an intravascular administration set to administer IV fluids and pharmaceuticals from a container to a patient's vascular system through a needle inserted into a vein. The device includes a drip chamber with a 15 µm filter and a spike to penetrate and connect the tubing to an I. V. bag or other infusion fluid container, tubing, flow regulator and a connector to connect the needle to the set. The administration set is for use under gravity and pressure conditions. The set is not intended nor indicated for use with blood or blood products.
Comparison of the Technological Features of the New Device and Predicate Device:	The administration set "Perfudrop® Air M-P with needle" is substantially similar to the lawfully marketed predicated device. Both sets are intended for administration of IV fluids and pharmaceuticals from a container to a patient's vascular system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 4 - 2004

Dr. Reinhard Hopf
Manager Regulatory Affairs
Clinico GmbH
Robert-Koch-Strasse 5
D-36251 Bad Hersfeld

Re: K041919
Trade/Device Name: Perfudrop® Air M-P with Sterile Hypodermic Needle 20 G, Model 48451606
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: July 12, 2004
Received: July 30, 2004

Dear Dr. Hopf:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K041919

Device Name: Perfudrop® Air With Sterile Hypodermic Needle 20 G

Indications For Use:

Perfudrop® Air M-P with Needle is an intravascular administration set to administer IV fluids and pharmaceuticals from a container to a patient's vascular system through a needle inserted into a vein.
The administration set is for use under gravity and pressure conditions.
The set is not intended nor indicated for use with blood or blood products.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number K041919